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PATENT
Docket No. 1400-004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
William J. Roberts	Group Art Unit: 1616
Entitled: "BIOAVAILABLE PRODRUGS OF ANDROGENIC STEROIDS AND RELATED METHOD"	Examiner: Qazi, Sabiha Naim
Serial No.: 10/053,505	
Filed: January 16, 2002	

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL

In response to the final Office Action dated February 25, 2004, the period for response having been extended by Petition to November 26, 2004, Applicant hereby submits this Brief on Appeal in triplicate, as required by 37 C.F.R. § 1.192. A Notice of Appeal was filed on May 25, 2004. Applicant respectfully submits that this appeal is proper, because the claims have been twice and finally rejected.

(1) REAL PARTY IN INTEREST

The real party in interest is Biotest Laboratories, LLC, a Colorado limited liability company.

(2) RELATED APPEALS AND INTERFERENCES

Applicant is unaware of any related appeals and/or interferences that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) STATUS OF THE CLAIMS

Claims 1-10 and 59-74 remain pending.

Claims 11-58 were cancelled.

Claims 1-10 and 59-74 stand rejected.

(4) STATUS OF AMENDMENTS FILED SUBSEQUENT TO FINAL REJECTION

Applicant has not filed any amendments subsequent to the final rejection of February 25, 2004.

(5) CONCISE EXPLANATION OF THE INVENTION

The invention is directed to compositions for increasing the concentration of a parent androgen in a subject *in vivo*. The parent androgen has a skeletal structure, specific carbons of which may be identified using the IUPAC ring and carbon numbering system for cholesterol and related compositions. The parent androgen includes a No. 4 carbon position and a No. 17 carbon position. It also includes a 17β-hydroxy group comprising a 17β-hydroxy oxygen appended to the 17 position and a 17β-hydroxy hydrogen appended to the 17β-hydroxy oxygen.

The composition comprises a substrate having the skeletal structure of the parent androgen. The substrate thus also comprises a 4 position and a 17 position corresponding to the 4 and 17 positions respectively of the parent

androgen. The substrate also comprises a carbon-carbon double bond at the 4 position. The skeletal structure of the parent androgen embodied in the substrate is selected from the group consisting of androst-4-ene-3α,17β-diol and androst-4-ene-3β,17β-diol.

The composition further comprises a promoiety appended to the 17β-hydroxy oxygen of the substrate as a substitute for the hydroxy hydrogen of the parent androgen, wherein the promoiety comprises an alkylcarbonate ester.

Claims 1 and 74 are independent, and claims 2-10 and 59-73 are dependent, depending directly or indirectly from claim 1. The dependent claims provide additional limitations on the composition. Claim 2, for example, provides that the alkulcarbonate ester has an alkyl chain length of less than 12. Claim 59 provides a similar chain length limitation. Claims 3-6 and 60-73 provide specific compositions or classes of compositions.

(6) CONCISE EXPLANATION OF THE ISSUES PRESENTED FOR REVIEW

The pending claims have been rejected under Section 102(b) based on four separate references. Therefore, there are four issues on appeal:

1. Whether the pending claims are anticipated under 35 U.S.C. § 102(b) by A-100 (4-androstene-diolethylcarbonate ester) based on the Internet document apparently published by MTE Nutrition;[1]

2. Whether the pending claims are anticipated under 35 U.S.C. § 102(b) by Chem Net, Taizhou Zingye Chemical Col.. Ltd., the project sold as 4-

1 A printout of a page from MTE Nutrition's Web site regarding the product A-100 was included with the Office Action.

androstenediol Methyl Carbonate and 4-androstenediol Ethyl Carbonate, based on a document cited by the Examiner;[2]

3. Whether the pending claims are anticipated under 35 U.S.C. § 102(b) by Twin Lab Products, "Andro Nitrate Fuel" 4-androstenediol Diethyl Carbonate ester, based on a document cited by the examiner apparently from Twin Labs;[3] and

4. Whether the pending claims are anticipated under 35 U.S.C. § 102(b) by A-100 (4-androstene-diol ethyl carbonate ester) "by Biotest Mag 10."

(7) GROUPING OF THE CLAIMS

Claims 1-10 and 59-73 stand or fall together.

(8) ARGUMENTS

The documents cited and applied by the Examiner in making these Section 102(b) rejections do not bear dates that pre-date Applicant's filing date. They are not prior art with respect to the pending claims, and the Examiner has failed to make a *prima facie* case based upon them.

MTE Nutrition's A-100

MTE Nutrition's Web page regarding A-100 contains no information as to when the product was first sold in the U.S. It merely states that the company has been in business since 1997. Therefore, based on the Web page itself

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2 The Office Action included printouts of Chem Net and Xingye's Web pages regarding these products.

3 A page from Fitness Connection Nutrition's Web site selling this product was included with the Office Action.

relied upon by the Examiner, that document does not demonstrate or prove, or even suggest that the compound disclosed in it has been in use or on sale in this country more than one year prior to the filing of this application. It does not qualify as prior art with respect to the pending claims.

In addition, the MTE Nutrition Web page regarding A-100 cannot be relied upon as prior art as a printed publication. As stated in Section 2128 of the Manual of Patent Examining Procedure, "prior art disclosures on the Internet or on an on-line database are considered to be publicly available as of the date the item was publicly posted. If the publication does not include a publication date (or retrieval date), it cannot be relied upon as prior art under 35 U.S.C. § 102(a) or (b) . . . ." Because the Web page does not contain a publication date or retrieval date, it cannot be the basis of a rejection under 102(b).

Taizhou Xingye Chemical Co. Ltd

These Web pages also fail to include publication or retrieval dates. In addition, there are no dates as to when these products were first used or sold in the United States. Therefore, these products allegedly manufactured by Xingye do not qualify as prior art and cannot be relied upon in a 102(b) rejection.

Twinlab's Andro Nitrate Fuel

The Web page documents relied upon by the Examiner in making this rejection also include no dates of when the product was first used or sold in the United States, nor is there a publication or retrieval date. Therefore, the

document forming the basis of this rejection has not been demonstrated to constitute valid prior art with respect to the pending claims, and cannot form the basis of a viable rejection under 102(b).

Biotest's Mag 10

Mag 10 is the product name (trademark) for a commercial product sold by Biotest Laboratories, LLC, which is the assignee of the present application. The Web page relied upon by the Examiner in making this Section102(b) rejection also does not demonstrate or show that the document or the product qualify as prior art with respect to the pending claims.

(9) CONCLUSION

The documents cited and relied upon by the Examiner in making these Section 102(b) rejections do not constitute valid prior art, based on their lack of dates showing the necessary and relevant dates. The Examiner therefore has failed to establish a *prima facie* case of unpatentability under Section 102(b). The rejections are misplaced and should be reversed.

Applicant is concurrently filing a Petition for Extension of Time to permit the timely filing of this Appeal Brief. A check for $935 is attached to cover the extension fee and the $170 fee for filing this Brief on Appeal. If this is deficient or if there are any additional fees due in connection with the filing of this Brief on Appeal, please charge the deficiency or fees to Deposit Account No. 501324. If the Petition is deficient in any way, please accept this paper as a Petition for Extension of Time so that the Brief is found timely and so that it is fully considered on the merits.

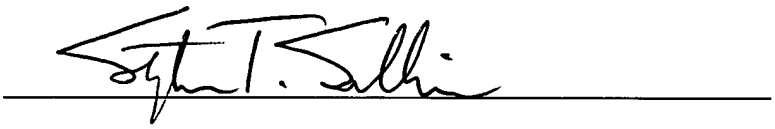
Dated: November 26, 2004

Respectfully submitted,

Stephen T. Sullivan
Reg. No. 32,444

CERTIFICATE OF EXPRESS MAILING

Express Mail Label No. EL 988283017 US
Date of Deposit: November 26, 2004
I hereby certify that this Brief on Appeal, in triplicate, Fee Transmittal for FY 2005 (2 copies) and check are being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed MS Appeal Brief - Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



APPENDIX

CLAIMS:

1. A composition for increasing the concentration of a parent androgen in a subject in vivo, the parent androgen having a skeletal structure including a 4 position and a 17 position and the parent androgen further having a 17β-hydroxy group comprising a 17β-hydroxy oxygen appended to the 17 position and a 17β-hydroxy hydrogen appended to the 17β-hydroxy oxygen, the composition comprising:

a substrate having the skeletal structure of the parent androgen comprising a 4 position and a 17 position corresponding to the 4 and 17 positions respectively of the parent androgen, the substrate comprising a carbon-carbon double bond at the 4 position, the skeletal structure of the parent androgen embodied in the substrate being selected from the group consisting of androst-4-ene-3α,17β-diol and androst-4-ene-3β,17β-diol; and

a promoiety appended to the 17β-hydroxy oxygen of the substrate as a substitute for the hydroxy hydrogen of the parent androgen, the promoiety comprising an alkylcarbonate ester.

2. A composition as set forth in claim 1, wherein the alkylcarbonate ester has an alkyl chain length of less than 12.

3. A composition as set forth in claim 1, wherein the composition comprises androst-4-ene-3,17β-diol 17β-alkylcarbonate.

4. A composition as set forth in claim 1, wherein the composition comprises androst-4-ene-3,17β-diol 17β-ethylcarbonate.

5. A composition as set forth in claim 1, wherein the composition comprises androst-4-ene-3,17β-diol 3,17β-di(alkylcarbonate).

6. A composition as set forth in claim 1, wherein the composition comprises androst-4-ene-3,17β-diol 3,17β-di(ethylcarbonate).

7. A composition as set forth in claim 1, further comprising a carrier.

8. A composition as set forth in claim 7, wherein the carrier comprises a solid carrier.

9. A composition as set forth in claim 7, wherein the carrier comprises a liquid carrier.

10. A composition as set forth in claim 7, wherein the carrier comprises a semi-solid carrier.

Claims 11-58 (cancelled).

59. A composition as set forth in claim 1, wherein the alkylcarbonate ester has an alkyl chain length of less than 11.

60. A composition as set forth in claim 1, wherein the alkylcarbonate ester comprises methyl carbonate.

61. A composition as set forth in claim 1, wherein the alkylcarbonate ester comprises propyl carbonate.

62. A composition as set forth in claim 1, wherein the alkylcarbonate ester comprises isopropyl carbonate.

63. A composition as set forth in claim 1, wherein the alkylcarbonate ester comprises butyl carbonate.

64. A composition as set forth in claim 1, wherein the alkylcarbonate ester comprises isobutyl carbonate.

65. A composition as set forth in claim 1, wherein the alkylcarbonate ester comprises t-butyl carbonate.

66. A composition as set forth in claim 1, wherein the alkylcarbonate ester comprises valeryl carbonate.

67. A composition as set forth in claim 1, wherein the alkylcarbonate ester comprises hexyl carbonate.

68. A composition as set forth in claim 1, wherein the alkylcarbonate ester comprises heptyl carbonate.

69. A composition as set forth in claim 1, wherein the alkylcarbonate ester comprises octyl carbonate.

70. A composition as set forth in claim 1, wherein the alkylcarbonate ester comprises nonyl carbonate.

71. A composition as set forth in claim 1, wherein the alkylcarbonate ester comprises decyl carbonate.

72. A composition as set forth in claim 1, wherein the alkylcarbonate ester comprises undecyl carbonate.

73. A composition as set forth in claim 1, wherein the alkylcarbonate ester comprises dodecyl carbonate.

74. A composition for increasing the concentration of a parent androgen in a subject in vivo, the parent androgen having a skeletal structure including a 4 position and a 17 position and the parent androgen further having a 17β-hydroxy group comprising a 17β-hydroxy oxygen appended to the 17 position and a 17β-hydroxy hydrogen appended to the 17β-hydroxy oxygen, the compound composition comprising:

a substrate having the skeletal structure of the parent androgen comprising a 4 position and a 17 position corresponding to the 4 and 17 positions respectively of the parent androgen, the substrate comprising a carbon-carbon double bond at the 4 position, the skeletal structure of the parent androgen embodied in the substrate being selected from the group consisting of androst-4-ene-3α,17β-diol and androst-4-ene-3β,17β-diol; and

a promoiety appended to the 17β-hydroxy oxygen of the substrate as a substitute for the hydroxy hydrogen of the parent androgen, the promoiety comprising an alkylcarbonate ester selected from the group consisting of a linear alkylcarbonate ester and a branched alkylcarbonate ester.